IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

JASON HARDEN, et al., individually and on behalf of those similarly situated, Plaintiffs, v. COLGATE-PALMOLIVE COMPANY, Defendant.	No. 25-cv-00362 Judge Andrea R. Wood
TANISIER CLAYBORNE, et al., individually and on behalf of those similarly situated, Plaintiffs, v. COLGATE-PALMOLIVE COMPANY, et al., Defendants.	No. 25-cv-04877 Judge Andrea R. Wood
JOSHUA COOK, individually and on behalf of those similarly situated, Plaintiff, v. COLGATE-PALMOLIVE COMPANY, Defendant.	No. 25-cv-05448 Judge Andrea R. Wood

MEMORANDUM OPINION AND ORDER

Plaintiffs in the three related cases presently before the Court are parents who allege that they purchased oral hygiene products containing fluoride for their children, all of whom were below the age of six. Although the U.S. Food and Drug Administration ("FDA") has found that

fluoride use poses unique safety risks to children under the age of six, Plaintiffs purchased a fluoride-containing oral hygiene product manufactured and sold by either Defendant Colgate-Palmolive Company ("Colgate") or Defendant Tom's of Maine, Inc. ("Tom's"), because each product was labeled and packaged in a way that made them believe that the product was specially formulated for children. In two of the cases, *Harden v. Colgate-Palmolive Co.*, No. 1:25-cv-00362, and *Cook v. Colgate-Palmolive Co.*, 1:25-cv-05448 ("Mouthrinse Actions"), Plaintiffs purchased fluoride mouthrinses even though they were contraindicated for use by their children under the age of six. And in the other case, *Clayborne v. Colgate-Palmolive Co.*, 1:25-cv-04877 ("Toothpaste Action"), Plaintiff purchased toothpastes containing fluoride and allowed their children under the age of six to brush with more than the amount recommended for children of that age. Because Plaintiffs in each action allege that Defendants' labeling and packaging of the fluoride products misled them about whether or how the products could be safely used by children under the age of six, they have brought putative class actions asserting claims for violations of the Illinois Consumer Fraud and Deceptive Business Practices Act ("ICFA"), 815 ILCS 505/1 *et seq.*, and other substantially similar state consumer-protection laws. Now, Defendants move to dismiss all three cases pursuant to Federal Rule of Civil Procedure 12(b)(6). (*Harden*, Dkt. No. 16, *Cook*, Dkt. No. 19, *Clayborne*, Dkt. No. 20.)[1] For the reasons that follow, Defendants' motions to dismiss the Mouthrinse Actions are denied, and their motion to dismiss the Toothpaste Action is granted.

[1] The *Cook* and *Clayborne* actions were originally assigned to different courts in this District. Those cases were subsequently reassigned to this Court. (*Harden*, 1:25-cv-00362 (Sept. 4, 2025).) The three cases were coordinated but not consolidated, and they remain separate cases. Thus, Defendants filed separate motions to dismiss in each case and those motions were briefed separately. Given the overlap in issues and arguments across the three cases and in the interest of judicial economy, the Court addresses each of the three motions to dismiss in a single ruling.

BACKGROUND

Each of the three actions involve Plaintiffs who bought a children's oral hygiene product manufactured and sold by either Colgate or Tom's, each of which allegedly marketed those products to the parents of young children. (Am. Class Action Compl. ("Harden ACAC") ¶ 1, *Harden*, 1:25-cv-00362 (Feb. 28, 2025); Am. Class Action Compl. ("Cook ACAC") ¶ 1, *Cook*, 1:25-cv-05448 (June 4, 2025); Class Action Compl. ("Clayborne CAC") ¶ 4, *Clayborne*, 1:25-cv-04877 (May 2, 2025).) For purposes of the motions to dismiss, the Court accepts as true all well-pleaded facts in each action's operative complaint and views those facts in the light most favorable to the respective Plaintiffs as the non-moving parties. *Hardimon v. Am. River Transp. Co.*, 95 F.4th 1130, 1133 (7th Cir. 2024). Because the allegations in the Mouthrinse Actions substantially overlap, the Court summarizes their allegations together before turning to separately summarize the Toothpaste Action's allegations.

I. Mouthrinse Actions

Plaintiffs in the Mouthrinse Actions are parents of young children who, at the time of their parents' purchase of the relevant mouthrinse product, were between the ages of two and five years old. (Harden ACAC ¶¶ 44–45, 52–53, 59–60, 67–68, 74–75, 82–83, 91–92; Cook ACAC ¶¶ 39–40.) Each Plaintiff purchased a fluoride mouthrinse manufactured and sold by either Colgate or Tom's[2] for their child, in reliance on the mouthrinses' packaging and labeling, which featured language and graphics that gave them the misimpression that the products were

[2] Tom's is a wholly owned subsidiary of Colgate. Despite Tom's being a separate corporate entity from Colgate, the *Harden* Plaintiffs failed to name Tom's as a Defendant in addition to Colgate. Nonetheless, the *Harden* parties have stipulated that the claims against Tom's in that action can be litigated against Colgate. (Pls.' Opp'n to Mot. to Dismiss at 15, *Harden*, 1:25-cv-00362 (June 6, 2025).) Meanwhile, *Cook* does not involve any Tom's products, while Tom's is named as a Defendant in *Clayborne*. For simplicity, the Court refers to Defendants collectively even when discussing arguments that may relate to only one of Colgate or Tom's.

specially formulated and safe for children of all ages. (Harden ACAC ¶¶ 2–4, 48, 55, 63, 70, 78, 86, 94; Cook ACAC ¶¶ 1–5, 43.)

A representative depiction of the Colgate mouthrinse's labeling from the *Harden* action is depicted below (the first image also contains a magnified view of the bottom part of the front label).

(Bladow Decl., Ex. A, *Harden*, 1:25-cv-00362 (Apr. 23, 2025), Dkt. No. 19-1; *see also* Harden ACAC ¶ 2.)[3] During the times relevant here, Colgate also sold the same product with front labels featuring Minions and Trolls, characters from popular children's movies.

[3] The images here and elsewhere in this opinion are taken from the exhibits to declarations in each action that Defendants submitted together with a separate request for judicial notice of those images or that the images be deemed incorporated into the complaint by reference. (*Harden*, 1:25-cv-00362 (Apr. 23, 2025), Dkt. Nos. 18–19; *Cook*, 1:25-cv-05448 (Aug. 8, 2025), Dkt. Nos. 21–22; *Clayborne*, 1:25-cv-04877 (Aug. 8, 2025), Dkt. Nos. 22–23.) The Court finds that the images from those declarations are properly considered at the motion to dismiss stage because they are central to the claims and thus incorporated into the complaints by reference. Indeed, the respective actions' complaints all include images of the relevant products, and Defendants' declarations simply provide the Court with higher quality images of those

(Bladow Decl., Ex. A, *Harden*, 1:25-cv-00362 (Apr. 23, 2025); *see also* Harden ACAC ¶ 190.)

Colgate has since discontinued sale of the Minions and Trolls mouthrinses in the United States. (Harden ACAC ¶ 190 n.89.) Also at issue in the *Harden* action is the Tom's children's mouthrinse shown below.

products. Plaintiffs do not oppose the Court's consideration of the higher quality images subject to the caveat that the Court not consider any magnified images of the labels as part of its reasonable consumer analysis. The Court agrees for purposes of its analysis below that the labels will be considered in the context of the product's entire packaging, but it will nonetheless sometimes provide enlarged images of the products' labels solely for ease of reference with respect to the label's contents.

(Bladow Decl., Ex. B, *Harden*, 1:25-cv-00362 (Apr. 23, 2025), Dkt. No. 19-2; *see also* Harden ACAC ¶¶ 3, 32, 194.)

At issue in *Cook* is the Hello Kids Fluoride Rinse, which is a mouthrinse sold under the Colgate-owned brand Hello Products. (Cook ACAC ¶ 1.) Packaging for the Hello mouthrinse's wild strawberry and bubble gum flavors is depicted below.

hello
naturally friendly
kids fluoride rinse
anticavity + no alcohol
wild strawberry
natural flavor
rinses away stuff brushing misses.
prevents cavities.
tastes awesome.
16 FL OZ (1 PT) 473 mL

your swish come true.
hooray, a kids anticavity rinse that's thoughtfully formulated with wild strawberry natural flavor and xylitol. it prevents cavities, strengthens teeth, and tastes so delicious they'll rush to rinse. learn more and smile more at helloproducts.com
vegan. no alcohol. no dyes.
no artificial sweeteners. no artificial flavors.
no SLS/sulfates. no brainer.

naturally friendly
hello
unicorn splash
anticavity fluoride rinse
bubble gum
natural flavor
prevents cavities
no alcohol
strengthens teeth
no artificial sweeteners. no dyes.
no SLS/sulfates. no brainer.
16 FL OZ (1 PT) 473 mL

your swish come true.
say hello to a magical anticavity rinse that tastes like rainbows and sunshine (aka bubble gum), and works brilliantly. it's thoughtfully formulated to help prevent cavities, strengthen teeth, and rinse away the nasty bits that little brushers may miss. and bonus, it's not tested on animals, real or imaginary.
#swishuponastar
vegan. no alcohol. no dyes.
no artificial sweeteners. no artificial flavors.
no SLS/sulfates. no brainer.
let's be friends.

(Bladow Decl., Exs. A, B, *Cook*, 1:25-cv-05448 (Aug. 8, 2025), Dkt. Nos. 22-1, 22-2; *see also* Cook ACAC ¶¶ 3, 110.)

Various aspects of the mouthrinses' packaging and labeling reveal how Defendants appealed to parents to purchase the products for their young children to use. (Harden ACAC ¶¶ 2–4, 190, 194; Cook ACAC ¶¶ 1–3, 110.) Indeed, all but the Hello bubble gum flavor mouthrinse have front labels that explicitly and prominently represent the products as for being for "kids" or "children." (*Id.*) And the mouthrinses are all sold in flavors akin to fruit juice or candy, so as to better cater to children's tastes. (*Id.*) The products also employ bright colors, cartoon images, or playful language that tend to indicate that the products are intended to be used by and are safe for children. (*Id.*) Thus, the Colgate mouthrinse includes cartoon images, is sold in a "bubble fruit" flavor, and the rinse itself is purple; the Tom's mouthrinse describes its flavor as "silly strawberry" and claims to be derived from real fruit juice; and the Hello bubble gum flavor is labeled as "unicorn splash" with a bright color scheme evoking a rainbow. (*Id.*)

Yet, even as the mouthrinses are advertised to children of all ages, the fluoride in them makes them unsafe for young children to use. (Harden ACAC ¶ 4; Cook ACAC ¶ 5.) In particular, the FDA has determined that fluoride mouthrinses "are not indicated for use in children under 6 years of age on an [over-the-counter] basis" and "should not be within easy reach of any children." (Harden ACAC ¶ 6; Cook ACAC ¶ 8.) Likewise, organizations including the American Dental Association, the World Health Organization, the American Academy of Pediatrics, and the U.S. Centers for Disease Control and Prevention have agreed that fluoride mouthrinse is not indicated for children under six years old. (Harden ACAC ¶¶ 7–10; Cook ACAC ¶¶ 9–12.) When excessive amounts are swallowed or ingested, fluoride can be toxic. (Harden ACAC ¶ 15; Cook ACAC ¶ 17.) Children under the age of six are at particular risk of

ingesting toxic amounts of fluoride from mouthrinses because their swallowing reflexes have not fully developed such that they are likely to swallow substantial amounts of the rinse accidentally even when instructed to spit. (Harden ACAC ¶¶ 128–32; Cook ACAC ¶¶ 51–55.) Moreover, the dangers from swallowing mouthrinse are heightened for young children since their smaller body size means that they receive a much higher fluoride dose by body weight than adults ingesting the same amounts. (Harden ACAC ¶¶ 133–34; Cook ACAC ¶¶ 133–34.) The risk that a child swallows a mouthrinse is exacerbated when it is flavored to taste like fruit or candy. (Harden ACAC ¶¶ 14, 36; Cook ACAC ¶¶ 15, 32.)

One of the risks that ingestion of fluoride poses to a child is dental fluorosis, a condition characterized by "a permanent, mottled discoloration of the teeth." (Harden ACAC ¶ 135; Cook ACAC ¶ 58.) Because the condition can only arise while a child's teeth are developing, the risk of dental fluorosis is unique to young children. (Harden ACAC ¶¶ 135–36; Cook ACAC ¶¶ 58–59.) The condition can range in severity, with mild forms causing permanent white lines or streaks on the teeth and more severe forms causing brown, gray, or black patches and pits on the teeth. (Harden ACAC ¶ 137; Cook ACAC ¶ 60.) Other potential hazards to young children from ingesting fluoride include gastrointestinal symptoms like diarrhea and vomiting, and even death in extreme cases. (Harden ACAC ¶¶ 144–66; Cook ACAC ¶¶ 68–91.)[4] Defendants themselves

[4] In each of Defendants' motions to dismiss, they have moved in the alternative to strike from each action's complaints the allegations elaborating on the various risk posed to young children from ingesting excessive fluoride. Under Federal Rule of Civil Procedure 12(f), a district court "may strike from a pleading an insufficient defense or any redundant, immaterial, impertinent, or scandalous matter." Motions to strike are generally disfavored and require the movant to "demonstrate that the challenged allegations are so unrelated to plaintiff's claim as to be devoid of merit, unworthy of consideration, and unduly prejudicial." *Wilkins v. City of Chicago*, 736 F. Supp. 3d 616, 626 (N.D. Ill. 2024). While the Court believes that Plaintiffs' complaints could have done without such extensive allegations regarding the harms that young children suffer from fluoride ingestion, such hazards are nonetheless relevant to Plaintiffs' claims alleging that Defendants misrepresent their oral hygiene products as kid-friendly when, in fact, those products pose unique safety risks to young children. As such, Defendants fail to meet their burden of showing that the drastic remedy of striking those allegations is appropriate. *Id.*

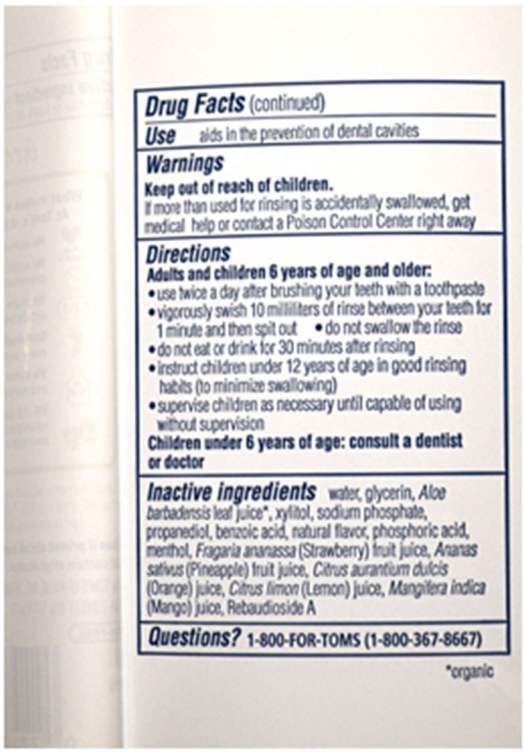
are aware that their mouthrinses are not safe for young children, as Colgate's website acknowledges that "children under six should not use mouthwash . . . as [they] may not have fully developed their swallowing reflexes and could swallow the mouthwash." (Harden ACAC ¶ 11; Cook ACAC ¶ 13.)

Recognizing that many consumers may be unaware of the risks posed by fluoride, the FDA requires fluoride mouthrinses to be properly labeled to ensure safe use. (Harden ACAC ¶¶ 25–26; Cook ACAC ¶¶ 28–29.) Consistent with the governing FDA regulations, each of the mouthrinse products here contain a bold-type warning to "[k]eep out of reach of children" and also advise that "[i]f more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center right away." (Harden ACAC ¶ 180 (quoting 21 C.F.R. § 355.50(c)(2); Cook ACAC ¶ 104.) The FDA also requires that the "principal display panel" of a fluoride mouthrinse prominently display the statement: "IMPORTANT: Read directions for proper use." (Harden ACAC ¶ 183 (quoting 21 C.F.R. § 355.55); Cook ACAC ¶ 106.) For mouthrinses containing either 0.02% fluoride ion or 0.05% sodium fluoride, like the Tom's and Hello rinses, the prescribed directions are as follows.

> Adults and children 6 years of age or older: Use once a day after brushing your teeth with a toothpaste. Vigorously swish 10 milliliters of rinse between your teeth for 1 minute and then spit out. Do not swallow the rinse. Do not eat or drink for 30 minutes after rinsing. Instruct children under 12 years of age in good rinsing habits (to minimize swallowing). Supervise children as necessary until capable of using without supervision. Children under 6 years of age: Consult a dentist or doctor.

(Harden ACAC ¶ 181 (quoting 21 C.F.R. § 355.50(d)(2)(i)); Cook ACAC ¶ 105.) The Hello mouthrinse includes the required warnings and directions on its back label, seen in the enlarged view of the wild strawberry flavor's back label below.

(Bladow Decl., Ex. A, *Cook*, 1:25-cv-05448 (Aug. 8, 2025).) The Tom's mouthrinse warnings and directions are found on a peel-back label underneath its back label, shown below.



(Bladow Decl., Ex. B, *Harden*, 1:25-cv-00362 (Apr. 23, 2025); *see also* Harden ACAC ¶ 33.)[5] A slightly different direction is applicable for mouthrinses containing 0.01% fluoride ion, like the Colgate rinse. Such mouthrinses must include the following directions:

> Adults and children 6 years of age and older: Use twice a day after brushing your teeth with a toothpaste. Vigorously swish 10 milliliters of rinse between your teeth for 1 minute and then spit out. Do not swallow the rinse. Do not eat or drink for 30 minutes after rinsing. Instruct children under 12 years of age in good rinsing habits (to minimize swallowing). Supervise children as necessary until capable of using without supervision. Children under 6 years of age: consult a dentist or doctor.

(Harden ACAC ¶ 182 (quoting 21 C.F.R. § 355.50(d)(2)(ii).) That direction appears on the Colgate mouthrinse's label as shown below.

Drug Facts

Active ingredient — **Purpose**
Sodium Fluoride 0.02% (0.01% w/v fluoride ion)..... Anticavity

Use aids in the prevention of dental cavities

Warnings
Keep out of reach of children. If more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Drug Facts (continued)

Inactive ingredients
Water, Glycerin, Propylene Glycol, Sorbitol, Poloxamer 407, Poloxamer 338, Flavor, PEG-40 Hydrogenated Castor Oil, Phosphoric Acid, Sodium Saccharin, Disodium Phosphate, Potassium Sorbate, Cetylpyridinium Chloride, Sucralose, Green 3, Red 33.

Questions? 1-800-468-6502

Directions
Adults and children 6 years of age and older:
- use twice a day after brushing your teeth with a toothpaste
- vigorously swish 10 mL (2 teaspoonfuls) of rinse between your teeth for 1 minute and then spit out
- do not swallow the rinse
- do not eat or drink for 30 minutes after rinsing
- instruct children under 12 years of age in good rinsing habits (to minimize swallowing)
- supervise children as necessary until capable of using without supervision

Children under 6 years of age: consult a dentist or doctor

(Bladow Decl., Ex. A, *Harden*, 1:25-cv-00362 (Apr. 23, 2025).)

Plaintiffs in the Mouthrinse Actions contend that the FDA-required warnings and labels on Defendants' mouthrinses were minimized on the back label or concealed, and are outweighed

[5] The Court notes that the Tom's label submitted by Defendants provides the directions required for a 0.01% fluoride ion concentration under 21 C.F.R. § 355.50(d)(2)(ii), even though the Harden ACAC alleges that its concentration makes the directions of § 355.50(d)(2)(i) applicable, (Harden ACAC ¶ 181 & n.7). Neither party addresses the discrepancy, and whether the label for Tom's mouthrinse is subject to the instructions of § 355.50(d)(2)(i) or (ii) is immaterial for present purposes.

by the other attributes of the products' packaging and labeling that explicitly and implicitly represent the mouthrinses as being for children. (Harden ACAC ¶¶ 190–91, 194–95; Cook ACAC ¶¶ 110–11.) Thus, each Plaintiff relied on those attributes and purchased one Defendants' children's mouthrinses believing that the product was specially formulated to be safe for their children under the age of six. (Harden ACAC ¶¶ 192, 196; Cook ACAC ¶ 112.) In reality, the fluoride content in a single dose of Defendants' children's mouthrinses can, if ingested, result in symptoms of fluoride toxicity. (Harden ACAC ¶¶ 16–18; Cook ACAC ¶¶ 18–20.) As such, the mouthrinses are contraindicated for children under the age of six. (Harden ACAC ¶¶ 193, 197; Cook ACAC ¶ 113.) Despite that contraindication, each Plaintiff alleges that Defendants' mouthrinses' labeling and packaging deceived them into purchasing the mouthrinses for their children under the age of six. (Harden ACAC ¶¶ 45, 48, 52, 55, 59, 61, 63, 67, 70, 74, 78, 82, 86, 90, 94, 191–92, 195–96; Cook ACAC ¶¶ 39, 43, 111–12.)

Had they known that Defendants' mouthrinses were unsafe for their under-six children, each Plaintiff contends that they would not have purchased the mouthrinses. (Harden ACAC ¶¶ 50, 57, 65, 72, 80, 88, 96, 193, 197; Cook ACAC ¶¶ 45, 113.) For that reason, they have brought their respective Mouthrinse Actions on behalf of themselves and a putative class, alleging that Defendants violated the ICFA, as well as the consumer protection statutes of California, New York, and several other states with substantially similar statutes.[6]

[6] The Harden ACAC also asserted claims for breach of implied warranty of merchantability and included claims from Plaintiffs who are residents of California and New York. (Harden ACAC ¶¶ 97–123, 223–42.) In their opening brief in support of their motion to dismiss the *Harden* action, Defendants argued that Plaintiffs failed to plead a viable warranty claim and that the Court lacked personal jurisdiction over the California and New York Plaintiffs' claims. Subsequently, Plaintiffs agreed to withdraw the warranty claim and the California and New York Plaintiffs' claims (though the claims for violating California and New York consumer fraud laws remain). (Pls.' Opp'n to Mot. to Dismiss at 15, *Harden*, 1:25-cv-00362 (June 6, 2025).) As such, the Court dismisses the warranty claim and the claims of Plaintiffs Kayla Smith, Susan Colby, Rena Drew, and Sandra Vatalaro from the Harden ACAC.

II. Toothpaste Action

In the Toothpaste Actions, Plaintiffs purchased for their children[7] under the age of six one of Defendants' kids-branded toothpastes. (Clayborne CAC ¶¶ 3, 30–31, 37, 39–40, 46–48, 53–55, 60–61, 148, 156, 159, 167–68.) Like most toothpaste sold in the United States, Defendants' children's toothpastes contain fluoride and their fluoride concentrations are equivalent to that of Defendants' standard adult brands. (*Id.* ¶¶ 1, 3, 147, 159.) And the same the health concerns from ingesting excessive amounts of fluoride discussed above with respect to the Mouthrinse Actions similarly apply to toothpastes containing fluoride. (*Id.* ¶¶ 1–2, 4, 20–26, 71–108.) But whereas the safety risks posed by the presence of fluoride in mouthrinses make them contraindicated for use by children under six, the same is not true for toothpastes containing fluoride.

Although fluoride toothpaste is contraindicated for children under the age of two, the FDA has determined that it is appropriate for children to use a fluoride toothpaste beginning at the age of two. (*Id.* ¶¶ 6–7, 110–15.) But given the risks ingesting fluoride poses to young children, the FDA requires the labels of fluoride toothpastes to include a bold-type warning to "[k]eep out of reach of children under 6 years of age" and to advise that "[i]f more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away." (*Id.* ¶ 137 (quoting 21 C.F.R. § 355.50(c)(1).) The labels must also include the following directions for use:

> Adults and children 2 years of age and older: Brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or doctor. Instruct children under 6 years of age in good brushing and rinsing habits (to minimize

[7] The Court notes that one of the Toothpaste Action Plaintiffs purchased the product for her grandchild to use during visits. (Clayborne CAC ¶¶ 36–38.)

> swallowing). Supervise children as necessary until capable of using without supervision. Children under 2 years of age: Consult a dentist or doctor.

(*Id.* ¶ 138 (quoting 21 C.F.R. § 355.50(d)(1)(i).) Further, given that children between the ages of two and six have not fully developed their swallowing reflexes, the American Dental Association and other health authorities recommend that children in that age range brush with smaller amounts of fluoride toothpaste than older children and adults. (*Id.* ¶¶ 8–10, 72, 111–15.) To guard against inadvertent ingestion of excessive amounts of fluoride, those health authorities recommend that children under the age of three apply only a smear of toothpaste to their toothbrush, and that children between the ages of three and six use only a pea-sized amount of toothpaste. (*Id.* ¶¶ 8–10, 111–15.) Colgate itself has echoed those recommendations. (*Id.* ¶ 11.)

Despite the apparent consensus that children ages two through six should brush with only a smear or pea-sized amounts of fluoride toothpaste, Plaintiffs in the Toothpaste Action allege that Defendants have aggressively marketed their children's fluoride toothpastes in a way that encourages young children to brush with the same amount of toothpaste as appropriate for those over the age of six. (*Id.* ¶¶ 12–13, 19.) To encourage such overconsumption, the packaging and labeling of Defendants' toothpastes contain many of the same attributes discussed above with respect to the mouthrinses that Plaintiffs claim misled them into believing that Defendants' toothpastes were safe for their young children to use at the same amounts as older children and adults. (*Id.* ¶¶ 12–17, 146–71.) Thus, the Colgate toothpaste label depicted below is expressly branded as being for "kids," contains colorful stars, is sold in a "bubble fruit" flavor, and displays an image of a toothbrush with a full strip of toothpaste, an amount suitable for older children and adults but not children under six.

(Bladow Decl., Ex. A, *Clayborne*, 1:25-cv-04877 (Aug. 8, 2025), Dkt. No. 23-1; *see also* Clayborne CAC ¶ 149.) And Colgate's "watermelon burst" liquid gel is sold in a fruity flavor, depicts a watermelon to emphasize its flavor, and displays the word "toothpaste" in rainbow colors on top of a bright yellow rectangle.

(Bladow Decl., Ex. B, *Clayborne*, 1:25-cv-04877 (Aug. 8, 2025), Dkt. No. 23-2; Clayborne CAC ¶ 156.) Colgate also sells its children's toothpaste in a pump that prominently displays a cartoon unicorn and touts its "bubble fruit" flavor, as seen below.

(Bladow Decl., Ex. C, *Clayborne*, 1:25-cv-04877 (Aug. 8, 2025), Dkt. No. 23-3; Clayborne CAC ¶ 162.) Finally, the below Tom's toothpaste package expressly labels itself as a "kid's" product, emphasizes that it is "natural," comes in a fruit flavor with the playful name "silly strawberry" (Tom's also offers "watermelon wiggle," "outrageous orange mango," "wild blueberry," and "fruitilicious flavors), and depicts a strawberry with superimposed smiley-face drawing.

(Bladow Decl., Ex. D, *Clayborne*, 1:25-cv-04877 (Aug. 8, 2025), Dkt. No. 23-4; *see also* Clayborne CAC ¶ 169.)

Each of the Toothpaste Action Plaintiffs bought one of the above products and allowed their children under the age of six to use the toothpaste without limiting them to only a smear or pea-sized amounts. (Clayborne CAC ¶¶ 29–65.) Had they not been misled by Defendants' toothpastes' packaging and labeling into believing that a full strip of toothpaste was an appropriate amount for their young children, Plaintiffs claim they would have made sure that their children used less toothpaste, as recommended. (*Id.* ¶¶ 178–80.) And those misrepresentations cost Plaintiffs' money equal to the additional amounts they spent on replacing Defendants' toothpastes over what they would have spent had their children brushed their teeth with only the recommended smear or pea-sized amounts of toothpaste. (*Id.* ¶¶ 177.) For those reasons, the Toothpaste Action asserts claims for violations of the ICFA and several other states' substantially similar consumer protection statutes.

DISCUSSION

To survive a motion under Rule 12(b)(6), "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). This pleading standard does not necessarily require a complaint to contain detailed factual allegations. *Twombly*, 550 U.S. at 555. Rather, "[a] claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Adams v. City of Indianapolis*, 742 F.3d 720, 728 (7th Cir. 2014) (quoting *Iqbal*, 556 U.S. at 678). Further, Rule 9(b) requires that a party alleging fraud must "state with particularity the circumstances constituting fraud," although "[m]alice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b). To state the circumstances of fraud with sufficient particularity, the plaintiff must allege "the who, what, when, where, and how: the first paragraph of any newspaper story." *DiLeo v. Ernst & Young*, 901 F.2d 624, 627 (7th Cir. 1990).

Defendants seek to dismiss both the Mouthrinse Actions and the Toothpaste Action in their entirety. First, Defendants argue that all three actions are expressly preempted by the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 379r(a)(2). Even if not preempted, Defendants contend that the Mouthrinse Actions and Toothpaste Action all fail to adequately plead that Defendants made any false or misleading representations regarding their children's mouthrinses or toothpastes. Preemption is an affirmative defense that a plaintiff need not anticipate or circumvent in their pleadings and warrants dismissal at the pleading stage only when "'the allegations of the complaint itself set forth everything necessary to satisfy' preemption." *Williams v. Galderma Lab'ys, LP*, No. 24 CV 2222, 2024 WL 4213220, at *2 (N.D. Ill. Sept. 17, 2024) (quoting *Sidney Hillman Health Ctr. of Rochester v. Abbott Lab'ys, Inc.*, 782 F.3d 922,

928 (7th Cir. 2015)). For that reason, the Court will first determine whether the Mouthrinse Actions and the Toothpaste Action state a viable claim and then turn to address preemption to the extent necessary.

I. Deceptive Business Practices

In each of the three actions, Plaintiffs allege that Defendants made false and misleading representations about the suitability of their fluoride-containing oral hygiene products for use by children under the age of six, in violation of ICFA and similar state consumer protection laws. Since all named Plaintiffs are from Illinois, their claims arise under the ICFA and that is the statute on which the Court's analysis will focus. To state an ICFA claim, a plaintiff must allege: "(1) a deceptive or unfair act or practice by the defendant; (2) the defendant's intent that the plaintiff rely on the deceptive or unfair practice; and (3) the unfair or deceptive practice occurred during a course of conduct involving trade or commerce." *Wigod v. Wells Fargo Bank, N.A.*, 673 F.3d 547, 574 (7th Cir. 2012) (internal quotation marks omitted). An ICFA claim may be predicated on either deceptive or unfair conduct. *Robinson v. Toyota Motor Credit Corp.*, 775 N.E.2d 951, 960 (Ill. 2002). Here, Plaintiffs' claims allege deceptive acts or practices, and they are therefore subject to Rule 9(b)'s heightened pleading standard. *Vanzant v. Hill's Pet Nutrition, Inc.*, 934 F.3d 730, 738 (7th Cir. 2019).

Defendants contend that the Mouthrinse Actions and the Toothpaste Action must be dismissed for failing to adequately plead a deceptive statement on any product's label. Under the ICFA, "[a] label is deceptive if it is likely to mislead a reasonable consumer in a material respect, even if it is not literally false." *Beardsall v. CVS Pharmacy, Inc.*, 953 F.3d 969, 973 (7th Cir. 2020). This "reasonable consumer" standard "requires a probability that a significant portion of the general consuming public or of targeted consumers, acting reasonably in the circumstances, could be misled." *Bell v. Publix Super Markets, Inc.*, 982 F.3d 468, 474–75 (7th Cir. 2020)

(internal quotation marks omitted). In applying the standard, a court "should take into account all the information available to consumers and the context in which that information is provided and used." *Id.* at 477. "What matters most is how real consumers understand and react to the advertising." *Id.* at 476. Typically, whether a statement would deceive reasonable consumer is an issue of fact. *E.g.*, *Sneed v. Ferrero USA, Inc.*, 656 F. Supp. 3d 777, 783 (N.D. Ill. 2023). Nonetheless, "where plaintiffs base deceptive advertising claims on unreasonable or fanciful interpretations of labels or other advertising, dismissal on the pleadings may well be justified." *Bell*, 982 F.3d at 477.

A. Mouthrinse Actions

According to Plaintiffs in the Mouthrinse Actions, by explicitly and implicitly labeling their fluoride mouthrinses as a children's product, Defendants mislead reasonable consumers into believing that those products are safe to be used by children of all ages when, in fact, they are contraindicated for children under six. At the pleadings stage, the Court finds it plausible that a reasonable consumer would be deceived by Defendants' labeling and purchase one of their children's fluoride mouthrinses for use by a child younger than six years old.

As an initial matter, the front label of all but one of Defendants' products prominently features the word "kids" or "children's." And the Hello mouthrinse that is not explicitly labeled on the front as for children has a back label that makes clear that it is meant for "little brushers." (Bladow Decl., Ex. B, *Cook*, 1:25-cv-05448 (Aug. 8, 2025).) It does not strike the Court as unreasonable for a consumer to see a product labeled as being for kids or children and believe that it is appropriate for use by children of all ages. Other aspects of the products' labeling implicitly reinforce the impression that the mouthrinses are appropriate for kids of all ages. In particular, many of the products use cartoons like unicorns and characters from popular children's movies that can be reasonably interpreted as an effort to appeal to preschool-aged

children. Further, not only do the fluoride mouthrinses come in fruit- or candy-like flavors that appeal children's palates but they also use cutesy language to describe the flavors. Thus, the Tom's mouthrinses come in "silly strawberry" and the bubble-gum flavored Hello mouthrinse is described as "unicorn splash." The unicorn splash mouthrinse also describes itself on the front as "tast[ing] magical" and on the back as a "magical anticavity rinse that tastes like rainbows and sunshine (aka bubble gum)." (*Id.*)

At bottom, the Court cannot conclude at the pleading stage that a reasonable consumer would, without more, know to draw a line at the age of six when shopping for children's mouthrinse. It is not persuaded by Defendants' insistence that a reasonable consumer would understand that mouthrinse is an over-the-counter drug, and therefore such a consumer would not purchase Defendants' mouthrinses before consulting their back labels, all of which warn, as required by the FDA, that the product should be kept out of reach of children under six years of age and that children under six should not use without first consulting a dentist or a doctor. The Seventh Circuit has held that the "accurate fine-print" on a product's back label "does not foreclose as a matter of law a claim that an ambiguous front label deceives reasonable consumers. Many reasonable consumers do not instinctively parse every front label or read every back label before placing groceries in their carts." *Bell*, 982 F.3d at 476. And while *Bell* was discussing a food product, the Court does not believe its reasoning is limited to that context. Indeed, the Seventh Circuit in *Bell* observed more generally that "consumers are likely to exhibit a low degree of care when purchasing low-priced, everyday items," with the "low-cost groceries" at issue there falling within that broader category. *Id.* at 479. And there is not much to distinguish Defendants' mouthrinses from low-cost groceries, given that they are both low-cost and, as evidenced by Plaintiffs' purchases in this case, available at supermarkets. (*E.g.*, Harden

ACAC ¶ 46 (alleging that Plaintiff Harden purchased Tom's rinses at Walmart and Target stores).) As another court in this District explained in denying a motion to dismiss a substantially similar ICFA claim, a reasonable consumer is unlikely "to examine the back label to ensure that the . . . candy-flavored mouthwash depicting cartoon characters . . . is indeed safe for preschool children." *Gibson v. Perrigo Co.*, No. 25-cv-348, 2025 WL 2807671, at *4 (N.D. Ill. Oct. 2, 2025) (quoting *Bell*, 982 F.3d at 479).

Considering each of Defendants' fluoride mouthrinse's labeling as a whole, the Court concludes that a consumer could reasonably interpret Defendants' explicit and implicit labeling of their mouthrinses as a children's product to mean that the products are suitable for use by children under six. Certainly, it is not unreasonable or fanciful to believe that the word "kids" or "children" encompasses preschool or kindergarten-age children. For that reason, the Mouthrinse Actions plead a plausible ICFA claim.

B. Toothpaste Action

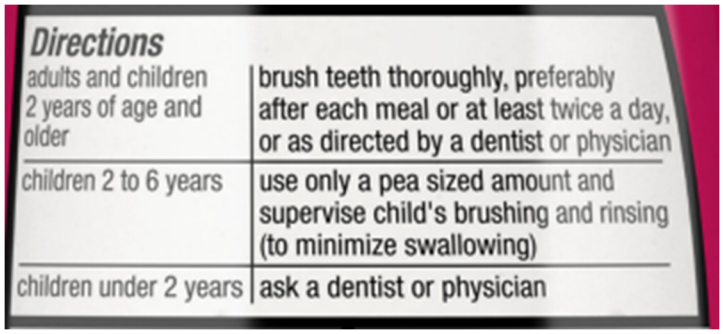
Whereas the Mouthrinse Actions straightforwardly allege that Defendants' representations of their mouthrinses as a kids product is misleading because the products are not suitable for some children, the Toothpaste Action does not object simply to Defendants' representing their product as being for children. Such a statement, by itself, is not similarly deceptive in the context of fluoride toothpastes, which the FDA has approved for use by children as young as two. (Clayborne CAC ¶¶ 6, 138.)[8] Thus, the Toothpaste Action Plaintiffs instead assert that the attributes of Defendants' toothpaste labels meant to appeal to kids also

[8] Although the FDA has recognized that fluoride toothpastes are contraindicated for children under two, (Clayborne CAC ¶ 6); *see also* 21 C.F.R. § 355.50(d)(1)(i) ("Children under 2 years of age: Consult a dentist or doctor."), and two of Plaintiffs in the Toothpaste Action bought toothpaste for their children under the age of 2 (Clayborne CAC ¶¶ 47, 54), the Toothpaste Action's claims are not based on allegations of Defendants marketing their toothpastes for use by children under two.

misleadingly induce parents of children under the age of six to allow their children to use more toothpaste than recommended.

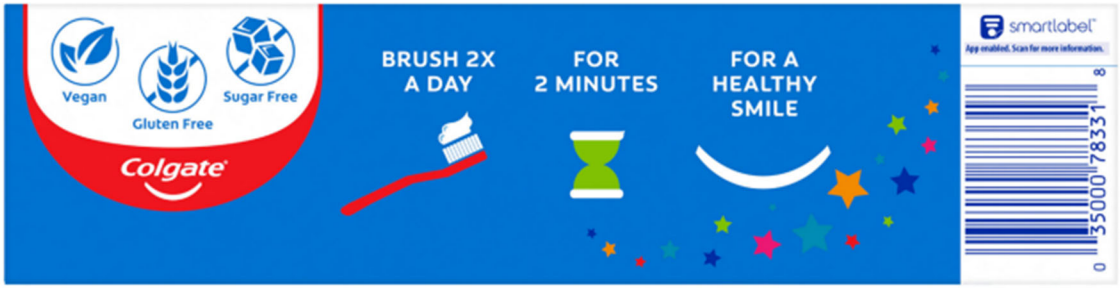
Stated succinctly, the deception alleged in the Toothpaste Action relates to the instructions for proper use of fluoride toothpaste by children under the age of six. In particular, children between the ages of two and six are recommended to use just a smear or pea-sized amount of toothpaste. Plaintiffs contend that they were deceived into allowing their under-six children to use more than those minimal amounts by aspects of the toothpastes' labeling depicting cartoon characters, touting their fruit or candy flavors, or otherwise representing the products as being for kids. However, with one exception that the Court will address below, none of the challenged aspects of the toothpastes' labels make any representation bearing on instructions for proper use. Put another way, labeling a product as being for "kids," depicting a cartoon unicorn, or offering flavors like "watermelon burst," "bubble fruit," or "silly strawberry" says nothing about the amount of toothpaste a child should use to brush. And Plaintiffs "can't bring a misrepresentation claim about a representation that isn't there." *Matthews v. Polar Corp.*, No. 22-cv-649, 2023 WL 4534543, at *7 (N.D. Ill. Mar. 22, 2023). The Court does not believe it would be reasonable for a consumer to infer instructions on proper usage from words and images that simply represent that the product is for kids or describe its flavor. *See id.* ("The presence of something is different than the amount of something. It is the difference between 'what' and 'how much.' No reasonable consumer would confuse the two."); *cf. Hamidani v. Bimbo Bakehouse LLC*, No. 22-cv-01026, 2023 WL 167513, at *3 (N.D. Ill. Jan. 12, 2023) ("Packaging that merely depicts or asserts the presence of an ingredient typically cannot lead a reasonable consumer to conclude that the product contains a certain amount of that ingredient.").

Notably, each of Defendants' children's toothpastes do include on its back label an instruction for children between the ages of two and six to "use only a pea sized amount," as shown below in a representative image of the Directions section of the Colgate watermelon burst liquid gel's back label.



(Bladow Decl., Ex. B, *Clayborne*, 1:25-cv-04877 (Aug. 8, 2025).) That instruction is not required by the FDA and Defendants apparently added it voluntarily to their products' back labels, presumably due to the guidance by health organizations such as the American Dental Association. While, as discussed above, the back label warning does not "immunize a defendant from a deceptive front label," it is still "one piece of 'all the information available to consumers' and is therefore relevant to determining whether reasonable consumers would be misled." *Sneed*, 656 F. Supp. 3d at 784. And where, as here, the back label is the only actual instruction on proper use by children ages two through six, it would be unreasonable for a consumer to ignore the back label's instructions and take guidance from words and images that make no representation whatsoever as to the appropriate amount of toothpaste for children to use.

As noted above, there is one product with a label that features instructions on use. In particular, one side of the Colgate kids cavity protection toothpaste's packaging features the following image.



(Bladow Decl., Ex. A, *Clayborne*, 1:25-cv-04877 (Aug. 8, 2025).) That label plainly instructs children to brush twice a day for two minutes. However, Plaintiffs do not claim that there is anything misleading about the language of that particular instruction. In fact, the label's instruction to brush twice a day simply repeats a portion of one of the instructions required by the FDA. (*See* Clayborne CAC ¶ 138 ("The FDA requires that all fluoride toothpastes provide the following directions: 'Adults and children 2 years of age and older: Brush teeth thoroughly, preferably after each meal or ***at least twice a day*** . . . .'" (emphasis added) (quoting 21 C.F.R. § 355.50(d)(1)(i))).)[9] Instead, Plaintiffs point to the image of a toothbrush with a full strip of toothpaste and argue that it misleadingly suggests to parents of children under six that their children can safely brush with a full strip of toothpaste. But it is readily apparent that the label's images simply provide a visual depiction of the instructions offered above. Thus, under "BRUSH 2X A DAY" is the image of the toothbrush with a full strip of toothpaste, under "FOR 2 MINUTES" is an hourglass, and under "FOR A HEALTHY SMILE" is a smile. The Court does not believe that a reasonable consumer would understand the images to make any representation beyond the written instructions that they illustrate. *See Matthews*, 2023 WL 4534543, at *9 ("Imagine . . . if a can of carbonated water simply said 'water,' with a picture of a glacier-

[9] Because the label's instruction to brush twice a day mirrors what is required by the FDA, it cannot serve as the basis for any ICFA claim. *See Bell*, 982 F.3d at 484 (explaining that where the FDA regulations protect a particular statement, the FDCA expressly preempts any state-law claim alleging that such statement is deceptive).

covered mountain. A consumer could not bring a claim that he or she expected that the water would come from a natural spring, or that the water came from a particular soft-flowing mountain stream in a majestic alpine peak in the French Alps."). Viewed in context, the toothbrush with a full strip of toothpaste is there only to represent the act of toothbrushing.[10]

Ultimately, the Toothpaste Action fails to state an ICFA claim because Defendants' toothpastes expressly instruct on their back labels that children between the ages of two and six should brush only with a pea-sized amount toothpaste and nowhere else do the labels contain any representation to the contrary. In arguing that various kid-friendly language and images mislead parents into believing that a full-strip is appropriate regardless of the child's age, the Toothpaste Action Plaintiffs "read[] far too much into the packaging." *Gardner v. Ferrera Candy Co.*, No. 22-cv-1272, 2023 WL 4535906, at *4 (N.D. Ill. Mar. 22, 2023). "Consumers cannot impose content that isn't there, and impute meaning that is not fairly derived from the labeling itself." *Matthews*, 2023 WL 4534543, at *9. Because that is what the Toothpaste Action attempts to do, it is dismissed for failure to state a claim.

II. Express Preemption

Having determined that the Mouthrinse Actions state viable claims for relief, the Court now turns to consider whether they are nonetheless preempted by the FDCA. The doctrine of preemption stems from the U.S. Constitution's Supremacy Clause, which provides that "[t]his

[10] The Court acknowledges that its analysis is at odds with the decision of another court in this District, *Gurrola v. Procter & Gamble Co.*, 1:25-cv-00358 (N.D. Ill. Oct. 31, 2025), which Plaintiff introduced as a supplemental authority. (Pl.'s Second Mot. for Leave to File Suppl. Authority, *Clayborne*, 1:25-cv-04877, Dkt. No. 39 (Nov. 4, 2025).) In that case, as here, the plaintiffs alleged that the defendant labeled its children's fluoride toothpaste to induce overconsumption by children under six. And the district court found that whether an image of a full strip of toothpaste combined with cartoon imagery and candy flavoring could mislead a reasonable consumer into overusing toothpaste was a fact issue that could not be resolved at the pleading stage. Respectfully, this Court is not persuaded by the *Gurrola* decision and notes that its analysis on this point was relatively cursory.

Constitution, and the Laws of the United States which shall be made in Pursuance thereof . . . shall be the supreme Law of the Land." U.S. Const. art. VI; *McHenry County v. Raoul*, 44 F.4th 581, 587 (7th Cir. 2022). "The underlying rationale of the pre-emption doctrine . . . is that the Supremacy Clause invalidates state laws that interfere with or are contrary to, the laws of congress." *Chi. & N. W. Transp. Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311, 317 (1981) (internal quotation marks omitted).

Preemption can be express where Congress "define[s] explicitly the extent to which its enactments pre-empt state law." *English v. Gen. Elec. Co.*, 496 U.S. 72, 79 (1990). Relevant here, the FDCA contains an express preemption provision that prohibits states from establishing any requirement "that is different from or in addition to, or that is otherwise not identical with, a requirement under" the FDCA. 21 U.S.C. § 379r(a)(2). "Put another way, the FDCA preempts 'state-law theories that impose requirements not identical to its own requirements.'" *Gibson v. Albertsons Cos.*, 754 F. Supp. 3d 793, 806 (N.D. Ill. 2024) (quoting *Benson v. Fannie May Confections Brands, Inc.*, 944 F.3d 639, 645 (7th Cir. 2019)). "It follows that, to avoid preemption, a state law claim of misleading labeling must allege a violation of the FDCA." *Smother v. Mentholatum Co.*, No. 24 CV 4155, 2025 WL 273437, at *1 (N.D. Ill. Jan. 17, 2025).

Among the FDCA's requirements is a prohibition on the misbranding of drugs. 21 U.S.C. § 331(b). And one of the ways a drug can be misbranded is where "its labeling is false or misleading in any particular." 21 U.S.C. § 352(a). For over-the-counter drugs like fluoride mouthrinses, "the FDA sets out a series of general rules and then it promulgates monographs containing specific rules for more specific categories of drugs." *Gibson*, 754 F. Supp. 3d at 806. "A monograph essentially sets out the federal requirements for a given category of nonprescription drugs." *Calchi v. TopCo Assocs., LLC*, 752 F. Supp. 3d 955, 966 (N.D. Ill.

2024). Following an extensive notice-and-comment process, "the monograph 'establish[es] conditions under which a category of [over-the-counter] drugs or a specific drug are generally recognized as safe and effective and not misbranded.'" *Id.* at 966–67 (quoting 21 C.F.R. § 330.10(a)(9)); *see also Williams*, 2024 WL 4213220, at *3 ("The upshot of these regulations is that a drug that complies with all monograph requirements is not misbranded."). The monograph for the labeling of anticaries drug[11] products is set forth at 21 C.F.R. § 355.50 ("Anticaries Monograph").

Defendants argue that the FDCA preempts the Mouthrinse Actions because the Anticaries Monograph does not prohibit the attributes of Defendants' mouthrinse labels that hold them out as a children's product. Moreover, they assert that the FDA carefully considered the risk of children accidentally ingesting fluoride and determined that the warnings required by the Anticaries Monograph were sufficient to address that risk. In short, Defendants' contention is that, because the aspects of the mouthrinses' labeling with which Plaintiffs take issue are not expressly prohibited by the Anticaries Monograph, Plaintiffs' state-law claims effectively seek to impose requirements different from or additional to what is required by the FDCA and are therefore preempted.

Some courts outside of this Circuit have interpreted the FDCA's express preemption provision as having as expansive of a scope as Defendants claim. *See, e.g.*, *Bowling v. Johnson & Johnson*, 65 F. Supp. 3d 371, 375 (S.D.N.Y. 2014) ("[P]reemption is certainly appropriate when a state law prohibits labeling that is permitted under federal law. But it is ***also*** appropriate when a state law prohibits labeling that is ***not prohibited*** under federal law. The standard, in

[11] An anticaries drug is "[a] drug that aids in the prevention and prophylactic treatment of dental cavities (decay, caries)." 21 C.F.R. § 355.3(c).

other words, is not whether a state law actively undermines federal law. It is whether state law diverges from federal law ***at all***."). However, the Seventh Circuit has taken a different approach. In particular, it has distinguished between claims in which a plaintiff "attempt[s] to use state law to require that disclosure language be ***added*** to a food label when federal regulations did not explicitly require it," which are preempted, and those in which the plaintiff "seek[s] only to stop defendants from voluntarily adding deceptive language to federally permitted labels," which are not preempted. *Bell*, 982 F.3d at 484. Under the Seventh Circuit's approach, "when a plaintiff's complaint concerns a requirement already imposed by the FDCA or an aspect of a defendant's labeling that the FDCA does not speak to, preemption does not apply." *Gibson*, 2025 WL 2807671, at *5.

The Mouthrinse Action Plaintiffs contend that their state-law claims are not preempted because they do not seek to compel Defendants to add any language to their labels but only challenge voluntarily added deceptive statements about the mouthrinses' suitability for children under six. The Court agrees. At bottom, the Mouthrinse Actions argue that it is deceptive for Defendants to package and label their mouthrinses as a product for children generally when the Anticaries Monograph requires that those products instruct children younger than six to "consult a dentist or doctor" before use. 21 C.F.R. § 355.50(d)(2)(i), (ii). Those directions embody the FDA's judgment that fluoride mouthrinses "are not indicated for use in children under six years of age on an [over-the-counter] basis." Anticaries Drug Products for Over-the-Counter Human Use; Final Monograph, 60 Fed. Reg. 52474, 52486 (Oct. 6, 1995). Accordingly, the Mouthrinse Actions allege that it is misleading for Defendants to market their mouthrinses to kids or children of all ages when the FDA has deemed them suitable only for children over the age of six. As such, the Mouthrinse Actions are not preempted because their claims are fully consistent with the

FDCA's regulations for fluoride mouthrinses. This Court's conclusion is in accord with another court in this District that have considered substantially similar claims regarding the deceptive labeling of children's mouthrinses. *Gibson*, 2025 WL 2807671, at *6 ("Plaintiffs . . . are seeking a ruling that Defendants alter their packaging so that it abides by the FDCA, which prohibits labeling that is 'misleading in any particular,' see 21 U.S.C. § 352, and requires that the 'advertising for [the children's mouthrinse] prescribes, recommends, or suggests its use only under the conditions stated in the labeling,' one condition being that it should only be used by children six and up, 21 C.F.R. § 330.1. So Plaintiffs' claims are not preempted by the FDCA.").[12]

CONCLUSION

For the foregoing reasons, Defendants' motions to dismiss the Mouthrinse Actions (*Harden*, Dkt. No. 16, *Cook*, Dkt. No. 19) are denied, and their motion to dismiss the Toothpaste Action (*Clayborne*, Dkt. No. 20) is granted. The Complaint in the Toothpaste Action, *Clayborne*, 1:25-cv-04877, is dismissed without prejudice to Plaintiffs in that action filing an amended complaint that remedies the deficiencies discussed above, if they can do so consistent with this memorandum opinion and the requirements of Federal Rule of Civil Procedure 11.

ENTERED:

Dated: March 27, 2026

Andrea R. Wood
United States District Judge

[12] Plaintiff in *Cook* filed a motion for leave to file a sur-reply, which was opposed by Colgate, the lone Defendant in that action. (*Cook*, Dkt. No. 31.) The Court finds the sur-reply unnecessary for purposes of its ruling and thus the motion is denied as moot.